

**IN THE DRAWINGS**

The attached three (3) replacement sheets of formal drawings, which include Figures 1-7, replace the originally filed seven (7) sheets of drawings, as requested by the Examiner.

### REMARKS

Applicant respectfully requests reconsideration. Claims 1 and 3-36 were previously pending in this application. By this amendment, Applicant is canceling claims 3 and 21 without prejudice or disclaimer. Each of claims 1, 8, 12, 19, 26, 32 and 35 is being amended. New dependent claims 37-40 are being added. As a result, claims 1, 4-20 and 22-40 are pending for examination with each of claims 1, 19, 32 and 35 being an independent claim. No new matter has been added.

#### Claim 1

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,230,349 to Langberg (hereinafter, "Langberg").

Claim 1 recites a catheter shaft distal end having an insulating material, and an electrode having an exposed surface with a first diameter. According to claim 1, the first diameter portion forms an angle with the insulating material. The Office Action points to an alleged first diameter portion of electrode (28) in the figure shown on page 4 of the Office Action and contends that this portion of electrode (28) forms an angle with the insulating material (see page 3, line 4 of the Office Action). This portion of electrode (28) is not shown to form an angle with insulating material. Instead, this portion of electrode (28) intersects with a tantalum tube (30), which is electrically conductive (see column 6, line 66 through column 7, line 20 of Langberg). Accordingly, withdrawal of the rejection of claim 1 is respectfully requested.

Without acceding to the propriety of the rejection, claim 1 has been amended to recite the features of dependent claim 3, namely that the insulating material, the first diameter portion and the transition face form a recessed region that allows blood to flow across the first diameter portion and the transition face when the electrode is placed in a blood flow. According to the Office Action, the device shown in Figure 4 of Langberg includes a catheter shaft having an insulating material, and an exposed electrode surface which has a first diameter portion, a second diameter portion and a transition face. In rejecting dependent claim 3, the Office Action contends that the insulating material, the first diameter portion and the transition face form a recessed region in Langberg, and

when the catheter of Langberg is placed in the vascular system, blood will flow through the recessed region.

While Figure 4 of Langberg appears to show a space between the conductive skirt (23) and the heat sink film (29), it is not clear whether the space is anything more than an artifact of the drawing. The specification does not describe any gap at this junction, and in fact the specification mentions that active electrode (28) and electrically insulating film heat sink 29 meet (see col. 6, lines 56-59).

Additionally, Langberg's description of the invention and its advantages clearly signifies that the provision of a recessed region at this junction is undesirable, and therefore the drawings and specification do not reasonably teach or suggest a recessed region to one of ordinary skill in the art. Langberg describes as undesirable the presence of a sudden transition in electrical properties at the boundary of the active electrode and the insulating catheter tube. At column 2, line 67 through column 3, line 3, Langberg, in discussing the prior art, states, "One undesirable feature associated with such a state-of-the-art catheter is a formation of hot spots along the circular junction of the active electrode with the insulating catheter tube due to a sudden transition of electrical properties at the boundary." At column 3, lines 54-61, Langberg states, "The invention further comprises a current equalizing coating for gradual transition of electrical properties at a boundary of a metallic active electrode and an insulating catheter tube. The current equalizing coating controls current density and the distribution of tissue heating. Absence of an abrupt transition in the electrical properties at the catheter tissue boundary, smoothes heat generation and reduces hot spots in tissue."

If a recessed region were in fact provided in the catheter of Figure 4, a sudden transition of electrical properties would be present at the juncture of active electrode (28) and electrically insulating heat sink film (29). As referenced above, one of the primary goals of Langberg is to avoid sudden transitions of electrical properties at the junction of the active electrode with the insulating catheter tube, and therefore Langberg does not teach or suggest a recessed region at the juncture of the insulating material and the electrode to one of ordinary skill in the art.

Notwithstanding Langberg's lack of description of any recessed region, claim 1 is being amended to recite that the insulating material, the first diameter portion and the transition face form a recessed region that allows blood to flow across the first diameter portion and the transition face

when the electrode is placed in a blood flow. Even if Langberg does teach the existence of a space between conductive skirt (23) and heat sink film (29), which is not conceded, Langberg does not describe a size of the space or a functionality of the space, and therefore does not teach the provision of a recessed region at this junction which is sufficient to allow for a flow of blood within the recessed region.<sup>1</sup> Accordingly, withdrawal of the rejection of claim 1 is respectfully requested.

Each of claims 4, 5 and 7-18 depends directly from claim 1, and withdrawal of the rejections of these claims is respectfully requested for at least the same reasons provided above for claim 1.

#### Claim 19

Claim 19 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Langberg in view of U.S. Patent No. 5,230,349 to Lennox (hereinafter, "Lennox").

According to the Office Action, Langberg does not disclose that an exposed electrode surface of the first diameter portion is parallel to the second diameter portion of the electrode. To cure this deficiency, the Office Action points to Lennox and contends that it would have been obvious to modify the Langberg catheter with the catheter tip disclosed by Lennox because doing so would create a flat bottomed channel to improve flow through the channel.

Applicant disagrees with the rejection. Langberg does not describe or suggest any flow through the space that is contended to be shown in the device of Figure 4, and therefore one of ordinary skill in the art would not be motivated to modify the device of Figure 4 to improve channel flow. Additionally, neither Langberg nor Lennox teaches that a flat bottomed channel would improve channel flow. If the Examiner maintains the rejection of claim 19, Applicant respectfully requests an indication of what specific teachings are being relied upon for these aspects of the rejection.

The Office Action further states that "since applicant does not give any criticality for parallel or slanted channels it is not patentably distinct from the current state of the art of catheter electrode tips." Applicant is not required to provide criticality for a claim feature. A device claim distinguishes the prior art by reciting a combination of structural limitations which results in a novel

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<sup>1</sup> See MPEP 2125, quoting *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue".

and non-obvious combination. If the rejection is maintained, Applicant respectfully requests that the Examiner point to the authority requiring the applicant to provide criticality for claim features. According to MPEP §2144.05(III), an applicant can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. But in the present application, the Office Action appears to be asserting a *prima facie* case of obviousness by incorrectly basing the rejection on an alleged lack of teaching of criticality of a claimed feature.

Without acceding to the propriety of the rejection, claim 19 is being amended to recite that the channel is sized to allow blood to flow across the channel base and the second sidewall when the electrode is placed in a blood flow. As discussed above regarding the rejection of claim 1, even if Langer discloses a space between the electrode (28) and heat sink film (29), Langberg does not describe a size of the space or a functionality of the space, and therefore does not teach a channel sized to allow blood to flow across the channel base and the second sidewall when the electrode is placed in a blood flow. Accordingly, withdrawal of the rejection of claim 19 is respectfully requested for at least this reason.

Each of claims 20 and 22-31 depends either directly or indirectly from claim 19, and withdrawal of the rejections of these claims is respectfully requested for at least the same reasons provided above for claim 20.

#### Claim 32

Claim 32 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Langberg in view of Lennox.

The Office Action points to an alleged channel in the figure reproduced on page 14 of the Office Action. According to the Office Action, Langberg discloses a width of the base of the channel that is at least one-tenth of the size of the largest diameter of the electrode and less than the smallest diameter of the electrode. The specification of Langberg does not describe any channel at the location noted in the Office Action, and even if a channel is present, Langberg is completely silent as to the dimensions of the channel. Accordingly, Langberg does not disclose that the width of the base of the channel is at least one-tenth of the size of the largest diameter of the electrode, and the rejection of claim 32 should be withdrawn.

Without acceding to the propriety of the rejection, claim 32 is being amended to recite that the channel base intersects the end of the insulating sheath. Support for this amendment may be found throughout the specification, including, for example at page 9, lines 9-10, page 10, lines 18-21 and in Figure 3. The alleged channel pointed to in the figure shown on page 14 of the Office Action does not include a base which intersects with the end of an insulating sheath. The channel base intersects tantalum tube (30) which is not an insulating sheath. Accordingly, withdrawal of the rejection of claim 32 is respectfully requested.

Each of claims 33 and 34 depends directly claim 32, and withdrawal of the rejections of these claims is respectfully requested for at least the same reasons provided above for claim 32.

#### Claim 35

Claim 35 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Langberg.

Without acceding to the propriety of the rejection, claim 35 is being amended to recite that the first diameter portion of the electrode forms a junction with the insulating sheath. The Office Action points to an alleged first diameter portion in the figure shown on page 9 of the Office Action. Even if a space is disclosed at the junction, this first diameter portion of the electrode does not form a junction with the insulation pointed to in the same figure. Instead, the first diameter portion forms a junction with tantalum tube (30) which is electrically conductive (see column 6, line 66 through column 7, line 20). Accordingly, withdrawal of the rejection of claim 35 is respectfully requested.

Claim 35 is being amended to additionally recite that the insulating sheath, the first diameter portion and the transition face form a recessed region that is sized to allow blood to flow across the first diameter portion and the transition face when the electrode is placed in a blood flow. As discussed above regarding the rejection of claim 1, even if Langer discloses a space between the electrode (28) and heat sink film (29), Langberg does not describe a size of the space or a functionality of the space, and therefore does not teach a channel sized to allow blood to flow across the channel base and the second sidewall when the electrode is placed in a blood flow. Accordingly, withdrawal of the rejection of claim 35 is respectfully requested for at least this reason.

Each of claims 6 and 36 depends from claim 35, and withdrawal of the rejection of claim 6 is respectfully requested for at least the same reasons provided above for claim 35.

New dependent claims

Each of claims 37-40 is being added to depend from independent claims 1, 19, 32 and 35, respectively. Claim 37 recites that the catheter further comprises an abrupt change in electrical properties at the junction of the ablation electrode and the distal end of the shaft. Each of claims 38 and 39 recite that the catheter further comprises an abrupt change in electrical properties at the junction formed by the ablation electrode with the insulating material. Claim 40 recites that attaching the electrode to the shaft comprises forming an abrupt change in electrical properties at the junction of the electrode with the insulating sheath.

Support for these new dependent claims may be found throughout the specification, including, for example, at page 6, lines 16-17.

**CONCLUSION**

In view of the above amendment, applicant believes the pending application is in condition for allowance and a Notice of Allowance is respectfully requested. If the Examiner believes that minor clarifying amendments to the claim would be helpful, the Examiner is requested to call the undersigned at the telephone number listed below.

The Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825 under Docket No. B1075.71018US01 from which the undersigned is authorized to draw.

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Respectfully submitted,

By 

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